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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,204	07/23/2003	Carl Gustav Figdor	89 DIV-2	8377

7590 10/04/2006

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EXAMINER	
HORNING, MICHELLE S	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/625,204	FIGDOR ET AL.	
	Examiner	Art Unit	
	Michelle Horning	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *9-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 15-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is responsive to communication filed 7/31/2006. The status of the claims is as follows: claims 1-23 are pending, claims 9-14 are drawn to non-elected species and claims 1-8 and 15-23 are under current examination.

Objection to Specification

The disclosure is objected to because of the following informalities: the specification states that the amino acid sequence set forth in SEQ ID NO:2 is 98% identical to a sequence identified by the prior art reference Curtis et al (1992) while Example 4 of the instant specification states the two sequences are 100% homologous; this is both incongruent and misleading. Sequence alignment by the current Examiner shows that they are indeed 100% homologous. It is further noted that post art by the Inventors (Geijtenbeek et al, 2000) states that the sequence "proved 100% identical to the deduced amino acid sequence of the HIV-1 envelope glycoprotein gp120 binding C-type lectin (Curtis et al., 1992)" (see Results).

Appropriate correction is required.

Claim Rejections

35 U.S.C. 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 and 15-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for at most and at best, a method of increasing some immune response by administering a compound that binds to DC-SIGN, does not reasonably provide enablement for this method to include all C-type lectins found on the surface of all dendritic cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims. Enablement is considered in view of the *Wands* factors (MPEP 2164.01(a)).

Nature of the Invention. The claims are drawn to a method of increasing an immune response in human by administering a compound that binds any C-type lectin receptor on a dendritic cell, excluding DEC-205 receptor.

State of the prior art. Curtis et al (1992) identified an HIV-1 envelope gp120 binding protein in human placenta as a membrane-associated mannose binding receptor (C-type lectin). This protein is 100% homologous to the amino acid sequence set forth in SEQ ID NO:2 of the instant application. Further, Curtis et al showed that antibodies can block gp120 binding to the differentiation antigen CD-4 expressed on COS cells. This prior art reference suggests that because the affinity of the mannose-binding protein for gp120 exceeds that of CD4, lectin could play a therapeutic role in effectively competing for gp120 and viral binding on those cells that also express CD4. While Curtis et al (1992) showed that the homologous binding protein is found in the membranes of human placental cells, namely, macrophages, they do not specifically mention the expression of this protein in dendritic cells. For reasons of record, it is noted

that Applicants have shown that the DC-SIGN protein is "specifically expressed by DC" (dendritic cells, example 5). Thus, it is highly conceivable that proteins are the same both structurally and functionally.

Breadth of the claims. The claims are extremely broad, encompassing any and all C-type lectins (except DEC-205) and any and all types of immune responses. The claims are not limited to a single lectin nor are they limited to specific immune responses.

Working examples. The examples are limited to characterizing SIGN-DC, including its molecular weight, expression and its interaction with ICAM-3. It is further noted that the examples are not drawn towards an immune response in an animal. The working examples are based on data from cultured cells and the type of immune response based on this data is nebulous throughout the working examples.

Guidance in the Specification. The specification provides little guidance in fulfilling the invention as so broadly claimed. The specification does not disclose the effect of any and all C-type lectins following binding of a compound. The guidance is based on theory and not actual data.

Predictability of the Art. There is no way of knowing whether any and all C-type lectins would retain the same immunological effect following the binding of some compound in an animal, if the effect in an animal is even known. Further, the physiological art in general is acknowledged to be unpredictable (MPEP 2164.03).

Amount of experimentation necessary. Besides the general expectation that it will require years of further research to fulfill the invention as broadly claimed, it would

require extensive research to understand the fundamental biology of the system. Much of the work is left for others to complete.

For the reasons discussed above, it would require undue experimentation for one skilled in the art to use the claimed methods.

35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Eck et al (1999). The limitations of the claims are: 1) a method for increasing an immune response comprising administering a compound; 2) wherein the compound includes a plant lectin; and 3) wherein the compound generates an immune response against tumor cells.

Eck et al teach that extracts containing lectins from mistletoe leaves are widely used for adjuvant therapy and immunostimulation. Further, this reference discloses insight into the mode of action of this cytotoxic plant protein on tumor and immune cells following administration to a subject (see introduction and discussion). Given that this reference meets the limitations above, these claims are rejected.

Claims 1, 2, 4, 6, 7, 8 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Yan et al (1999). The limitations of the claims are: 1) a method for increasing an immune response comprising administering a compound to a mammal,

including a human; 2) wherein the compound includes a sugar; and 3) wherein the compound binds a cancer antigen and generates an immune response against tumor cells.

Yan et al disclose a method in which administration of beta-glucan (or polysaccharide) induces tumoricidal activity in mice by binding to a lectin domain. Further, this reference teaches that the cell-mediated toxicity is regulated by tumor-specific Abs that target only tumor cells with iC3b receptors. Yan et al also disclose that beta-glucans are specific response modifiers and have been used in patients for tumor immunotherapy.

CONCLUSION

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle Horning whose telephone number is 571-272-9036. The examiner can normally be reached on Monday-Friday, 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 570-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for unpublished application is available through Private PAIR only. For more information about PAIR system, see htt://pair-direct.uspto.gov. Should you have questions on

access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michelle Horning
Patent Examiner

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